Remarks

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, claim 1 has been amended and new claims 29-30 have been added so that claims 1, 2, 4-15, 17-27, and 29-30 will be pending. Presently, claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27, and 29-30 are being examined and claims 5-10, 13, and 21-26 have been withdrawn from consideration as being directed to non-elected inventions. Support for the amendment to claim 1 regarding the liquid composition can be found in the specification at least at page 19, lines 31 to 32. Support for new claims 29-30 can be found in the specification at least at page 21, lines 23 to 25. The specification recites various pH ranges which establish multiple pH data points, i.e., 1, 1.5, 2, 3, 3.5, and 4, which when taken as a whole provide written description support for new claim 30. Specifically, the pH data points of 1, 1.5, 2, and 3 provide four pH values which support a pH of 3 or below. Accordingly, no new matter has been presented by the proposed amendments and entry of new claims.

Claims 1, 2, 4, 11, 12, 14, 15, 17-20, and 27 stand rejected under 35 U.S.C. § 112, first paragraph for lack of written description. This rejection is respectfully traversed.

The prior amendment to claim 1 regarding a pH value in the range of from 1 to 3 finds support in the specification at least at page 21, lines 23 to 25. The specification recites various pH ranges which establish multiple pH data points, i.e., 1, 1.5, 2, 3, 3.5, and 4, which when taken as a whole provide written description support for the pH value in the range of from 1 to 3 of claim 1. Specifically, the pH data points of 1, 1.5, 2, and 3 provide four pH values which support a pH value in the range from 1 to 3, i.e., each end point and two intermediate values of the claimed range and which establish that the inventors had possession of the claimed invention at the time the application was filed. Accordingly, no new matter has been presented by the prior amendment to claim 1.

Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph for lack of written description and allowance of the pending claims is respectfully requested.

Claims 1, 2, 4, 11, 12, and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,300,283 to Prencipe et al. ("Prencipe"). This rejection is respectfully traversed.

Prencipe discloses toothpaste or dental gel compositions having a pH within the range of about 4 to about 9 (column 2, lines 17-18). The compositions of Prencipe may contain a polymeric thickening agent containing acid groups (column 4, lines 18-29), however, the compositions are not desensitizing agents.

Thus, liquid compositions including a non-polymeric acid and having a pH within the claimed range are not disclosed or suggested by Prencipe. The Examiner refers to column 4, lines 22 to 25, 31, 48 to 55; column 5, lines 39 to 43; and column 6, lines 43 to 47 in support of the position that the sulfonic acid of Prencipe is a monomeric acid. Applicants disagree. These passages are clearly concerned with polymeric acids. These passages read as follows:

> Column 4:
> "The above-discussed linear viscoelastic properties of the dentifrice compositions of this invention are fundamentally provided by the defined synthetic linearly viscoelastic cross-linked polymeric thickering agents which generally have a molecular weight (M.W.) of about 1,000 to about 5,000,000. The homopolymers and copolymers (from 2, 3 or more monomers) to be cross-linked are generally anionic comprising a chain or backbone containing repeating units each preferably containing at least one carbon atom (typically only carbon atoms in the chain or backbone) and preferably at least one directly or indirectly pendant monovalent acidic group, e.g. sulfonic, phosphinic, or preferably phosphonic or carboxylic, or salt thereof, e.g. alkali metal or ammonium. It is ordinarily desirable that the repeating units constitute at least about 10%, preferably at least about 50%, more preferably at least about 80% up to 95% or 100% by weight of the polymer. Preferably, about 0.02 to about 5%, more preferably about 0.1 to about 2.5% of the cross-linked polymer is employed in the dentifrice compositions herein.
>
> [...]
>
> These synthetic anionic polymeric polycarboxylates are often per se employed in the form of their free acids or preferably partially or more preferably fully neutralized water soluble or water swellable (hydratable,

gel/forming) alkali metal (e.g. potassium and preferably sodium) or ammonium salts. Preferred are 1:4 to 4:1 copolymers of maleic anhydride or acid with another polymerizable ethylenically unsaturated monomer, preferably methyl vinyl ether/maleic anhydride (MVE/MA) having a molecular weight (M.W.) of about 30,000 to about 1,000,000."

Column 5:
"According to another preferred embodiment of this invention, the required cross-linked polymer is derived from a polymer containing repeating units in which one or more phosphonic acid groups are bonded to one or more carbon atoms in the polymer chain. Examples of such polymers are poly (vinyl phosphonic acid) containing units of the formula:..."

Column 6:
"As illustrative of polymers containing phosphinic acids and/or sulfonic acid groups, there may be mentioned polymers and copolymers containing units or moieties derived from the polymerization of vinyl or allyl phosphinic and/or sulfonic acids."

In the passages cited by the Examiner there is absolutely no reference to monomeric acids, thus Prencipe do not teach compositions including a non-polymeric acid as required by claim 1.

Furthermore, Prencipe relates to toothpastes and dental gels having viscoelastic properties (column 1, lines 6 to 8). In contrast, claim 1 of the present invention recites a liquid composition. The compositions of the present invention result in the co-precipitation of proteins, organic polymers and calcium within the dentinal tubules. Only liquid compositions can penetrate into these tubules where the polymers of the compositions mix with proteins and calcium of the dentinal fluid followed by precipitation and plug formation. The highly viscous compositions disclosed by Prencipe cannot penetrate into the dentinal tubules and do not result in the formation of plugs which have a long lasting effect.

Additionally, Prencipe fails to disclose or suggest a composition having a pH within the claimed ranges. Accordingly, for at least the reasons noted above, Prencipe fails to

disclose or suggest each and every claim limitation. Withdrawal of the record rejection and allowance of the pending claims is respectfully requested.

Claims 1 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 99/52498 to Pashley et al. ("Pashley"). This rejection is respectfully traversed.

Pashley discloses a method of reducing dentine sensitivity and compositions therefore. This method includes (i) applying an effective amount of an acid to a dentine surface to form a treated surface, and (ii) administering an effective amount of an acid oxalate to the treated surface so as to occlude dentinal tubules beneath the dentine surface. The method may optionally include the subsequent application of a suitable bonding agent (page 3, lines 12-15).

The acid treatment can be carried out with any acid etchant that is capable of removing an effective amount of calcium phosphate to an effective depth beneath the dentine surface (page 7, lines 20-22). The acidic oxalate contains an oxalic acid salt and has a pH of 4.0 (page 8, line 27 to page 9, line 7; page 11, lines 13-17).

Pashley is concerned with a method of reducing dentine sensitivity. However, Pashley describes the separate use of an acid followed by administering an acidic oxalate to the acid treated surface, i.e. a two-step process. Pashley clearly distinguishes between the strongly acidic acid etchant and the acidic oxalate which is titrated to a pH of 4.0. Pashley does not provide an incentive to combine the acid etchant and the acidic oxalate. To the contrary, it is demonstrated with reference to Figures 2 to 4 that the acid treatment results in an improved action of the acidic oxalate. If the acidic oxalate is directly applied to the tooth surface, crystals of calcium oxalate form on the tooth surface (page 4, lines 7-9). Only if the tooth surface is first treated with acid etchant the acidic oxalate is able to penetrate within the dentine tubules (page 4, line 23 to page 5, line 2).

The Examiner is of the opinion that the composition of Pashley contains non-polymeric acid oxalate. Rather, Pashley discloses compositions for reducing the sensitivity of teeth which comprise an acidic oxalate, i.e. a salt of oxalic acid and not organic acid itself (page 8, line 14 and 27). Thus, Pashley does not disclose compositions comprising free oxalic acid.

Furthermore, it is a well-known fact that oxalic acid does not precipitate proteins. For instance, U.S. 2008/0213906 clearly distinguishes between organic acids which have protein precipitating properties and organic acids which do not have protein precipitating properties (paragraphs [0071] and [0072] and claim 35 in combination with

claims 36 and 37). While some acids are found in both groups, see for instance acetic acid, oxalic acid is only mentioned in the group of organic acids, but not in the group of protein precipitating agents. This document confirms the general knowledge of a skilled person that oxalic acid does not precipitate proteins.

In addition, the compositions of Pashley preferably also have the form of a gel (page 9, line 4). It was surprisingly found by the present inventors that compositions according to presently amended claim 1 can be directly applied to the tooth surface and result in the formation of massive plugs which deeply penetrate into the dentinal tubules without the need for an acid pretreatment (page 36, Example 8, in particular lines 31-35 in combination with Figures 3 and 5; page 36, line 38 to page 37, line 8 and Figure 6). This is a significant improvement with regard to the method disclosed by Pashley in that a separate acid treatment is avoided.

Accordingly, Pashley does not disclose or suggest compositions including a non-polymeric acid and having a pH within the claimed range. Withdrawal of the record rejection and allowance of the pending claims is respectfully requested.

Claims 1, 2, 11, 12, 14-16, 19, and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,568,540 to Asano et al. ("Asano"). This rejection is respectfully traversed.

Asano relates to oral hygiene compositions which prevent and control mouth odor, calculus, plaque and caries and contain active zinc ions and fluoride ions (column 1, lines 5-12). These compositions contain a specific buffering system and have a pH of from about 3.5 to 6.0 (column 2, lines 28-29). A preferred buffering agent is sodium gluconate (column 3, lines 7-9). This buffering agent is used in all examples, i.e. in the examples no acid is used. Thus, Asano is not concerned with desensitizing agents.

Asano does not disclose or suggest compositions including a non-polymeric acid and having a pH within the claimed range. In particular, claims drawn to a composition maintaining the pH range of 1 to 3 distinguish the compositions of Asano which have a pH between 3.5 and 6.0 (see also column 3, lines 17-19). Moreover, the present claims which restrict the pH to a range of from 2 to 3 and to a range of 3 or below are further distinguished over Asano.

The present invention is further distinguished over Asano by the fact that Asano does not suggest the claimed composition. Although Asano discloses various ingredients which can be used in the preparation of the compositions of the present invention,

Asano does not make available or suggest the specific combination of the components of present claim 1. In order to arrive at the claimed compositions a skilled person would have to make numerous selections from the disclosure of Asano. For instance, Asano teaches the use of buffering agents comprising organic acids/salts but do not teach acids having protein and calcium-precipitating properties. Asano therefore fails to teach or suggest to combine such an acid with an organic polymer which has carboxyl and/or hydroxyl groups, a film forming component and a solvent. None of the specific examples of Asano is novelty destroying. The compositions disclosed in the examples contain large amounts of hydrated silica, sorbitol and thickeners and thus have a gel-like structure which does not have the composition or effect of the liquid compositions of the present invention.

Accordingly, for at least the reasons noted above, Asano fails to disclose or suggest each and every claim limitation. Withdrawal of the record rejection and allowance of the pending claims is respectfully requested.

Claims 1, 2, 4, 11, 12, 14, 15, 17-20, and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,004,538 to Hughes et al. ("Hughes") in view of Asano. This rejection is respectfully traversed.

As noted above, Asano discloses compositions having a pH of from about 3.5 to 6.0 and thus, does not disclose or suggest compositions including a non-polymeric acid and having a pH within the claimed range.

Hughes discloses oral compositions which include a dimethicone copolyol anti-plaque agent and a dimethicone copolyol surfactant (column 3, lines 26-28). Depending on the intended use, the compositions may include further components. For instance, denture cleansing compositions can also incorporate an effervescence generator, i.e., a material which in the presence of water releases carbon dioxide or oxygen with effervescence (column 8, lines 4-8). Such effervescence generators typically contain at least one alkali metal carbonate or bicarbonate in admixture with an organic acid (column 8, lines 13-23). Hughes discloses the use of acids only in combination with effervescence generators, i.e., in compositions including an acid and also an alkali metal carbonate or bicarbonate, that is a component which reacts with the acid to form carbon dioxide and thus neutralizes the acid. Although Hughes does not specify the pH of the compositions, it is evident that these compositions cannot have an acidic pH. Moreover, compositions including acid and carbonate or bicarbonate are only stable in solid form because acid and carbonate or bicarbonate will

immediately react in the presence of water (column 8, lines 35-37). Hughes does not disclose compositions which include a free acid in combination with a solvent.

Hughes discloses oral compositions for various purposes. Hughes discloses the use of acids only in combination with effervescence generators, i.e. compositions comprising an acid and a carbonate or bicarbonate which will form carbon dioxide upon contact with water. In this reaction the carbonate will neutralize the acid. The Examiner indicated that the language of the claims of the present invention did not exclude effervescence generators. It is believed that the claims as presently amended do exclude effervescence generators. The compositions of Hughes must be solid because the carbonate and the acid will immediately react in a liquid phase. Since newly amended claim 1 is directed to liquid compositions the presence of effervescence generators is thereby excluded.

Furthermore, the Examiner's combination is based on hind sight. A skilled person not knowing the present invention would not have an incentive to combine the components as defined in present claim 1. The examples of Hughes disclose either denture cleansing tablets, i.e. solid compositions comprising an effervescence generator, or toothpaste/denture cleansing pastes which have a gel structure and are not liquid. Furthermore, the toothpastes/denture cleansing pastes disclosed in Examples VI to VIII do not contain any fluoride and, therefore, a skilled person would not have adjusted the pH of these compositions to a range of 3.5 to 6 in order to stabilize the fluoride, as suggested by the Examiner.

For at least the reasons noted above, the proposed combination of Hughes and Asano would not render obvious the presently claimed invention. Accordingly, withdrawal of the record rejection is respectfully requested.

Claims 1, 2, 4, 11, 12, 14, 15, 17-20, and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,352,439 to Norfleet et al. ("Norfleet") in view of Asano and further in view of U.S. Patent No. 5,750,145 to Patell ("Patell"). This rejection is respectfully traversed.

The present invention pertains to compositions for the desensitization of teeth including an acid, an organic polymer, a film-forming agent, and a solvent having the recited properties. It has been found by the present inventors that these compositions deeply penetrate into dentinal tubules. By reaction with dentinal fluid proteins they form massive plugs and thus reduce the sensitivity of the teeth (page 20, lines 1 to 8 and 17 to 23 of the present application). To achieve the desired formation of a plug, it is necessary to use acids

having protein and calcium precipitating properties. The resulting formation of such plugs is surprising since acids usually have a sensitizing effect rather than a desensitizing effect (page 20, lines 7 to 8 of the present application).

The inventors have demonstrated that the compositions of the present invention result in the formation of massive plugs which deeply penetrate into dentinal tubules (page 36, Example 8, in particular lines 31 to 35 in combination with Figures 3 and 5; page 36, line 38 to page 37, line 8; and Figure 6 of the present application) even if the natural pressure of dentinal fluid is simulated. The desensitization agents of the present invention result in a long-lasting desensitization effect.

Formation of these plugs cannot be explained by the mere agglomeration of the polymers contained in the compositions. The experiments of the inventors noted above clearly show that the simultaneous precipitation of polymer, dentinal fluid proteins and calcium is responsible for the formation of the plugs.

In contrast, Norfleet discloses oral compositions, such as a tooth paste, including an effective anti-tartar proportion of polyphosphate, and a desensitizing or tooth pain inhibiting proportion of a tooth pain inhibiting potassium salt (column 1, lines 54 to 59). Preferably the compositions include a potassium salt of an anionic polymeric polycarboxylate (column 1, lines 64 to 68). These compositions may additionally contain diphosphonic acids and phosphonoalkane carboxylic acids or their alkali metal salts (column 2, lines 8 to 12). Copolymers, if initially in acidic form, are neutralized to a pH in the range of 6 to 8, preferably 7 (column 10, lines 3 to 6). Moreover, the pH of the overall composition is preferably also within the range of 6 to 8, more preferably 6.5 to 7.5 (column 10, lines 25 to 26). Norfleet theorizes that the presence of potassium ion in the composition aids in desensitizing the teeth in toothpastes and other oral compositions so that the teeth feel less pain when brushed (column 2, lines 17 to 21). Thus, Norfleet does not teach or suggest compositions having a pH within the claimed range.

According to Norfleet, acid components are neutralized and the pH of the compositions is adjusted to be in the range of 6 to 8. There is no reason to modify the compositions of Norfleet to adjust the pH within the claimed range. The compositions of Norfleet do not posses free acid having protein and calcium precipitating properties. Norfleet discloses toothpastes which have a pH in the range of 6 to 8, preferably 7 (column 10, lines 3 to 6). A skilled person would not have adjusted the pH of Norfleet to a range of 1 to 3 since this pH range is unusual for toothpastes. Furthermore, an acid pH is in clear contradiction to

the teaching of Norfleet and therefore a skilled person would not have considered a pH of 1 to 3 to be of any use when trying to modify the compositions of Norfleet. Moreover, this document is not concerned with liquid compositions.

As noted above, Asano discloses compositions having a pH of from about 3.5 to 6.0 and thus, does not disclose or suggest compositions including a non-polymeric acid having a pH within the claimed range. Asano provides no reason to lower the pH to a value within the claimed pH range.

Patell pertains to stabilized pharmaceutical compositions including gelatin-coated pharmaceutically active dosage units containing a therapeutically active ingredient which is subject to hydrolysis on storage as a result of moisture in the air or in one or more of the components of the dosage unit. Patell is especially concerned with the stabilization of analgesics such as gelatin-coated aspirin tablets (column 1, lines 5 to 12). Patell is cited for teaching film-forming agents. However, Patell in no way teaches or suggests adjusting the pH of the compositions disclosed by Norfleet to a pH within the claimed range. Accordingly, Patell fails to make up for the deficiencies of the Norfleet disclosure noted above.

It is asserted that the present amendment of claim 1 further distinguishes the claimed subject matter over these documents. The claimed compositions include a combination of four components which are all needed to achieve the desired action:

1. The acid is responsible for conditioning the enamel and the dentine surface, respectively. The acid removes dentine debris and abrasives from dentifrices from the openings of the tubules so that the tubules are accessible for the protein and calcium precipitating components as well as for the co-precipitating polymers of the compositions of the present invention. The acid initiates the protein and calcium precipitation.
2. Precipitation is enhanced by the organic polymers having carboxyl and/or hydroxyl groups.
3. The precipitation reaction of the present invention usually requires 15 to 30 minutes. During this time period the tubules are protected by a film which is formed by the film forming agents.

This film protects the precipitation process and can easily be removed by toothbrushing or eating. This film is not needed to block the tubules, rather they are blocked by the plugs formed by the precipitation reaction of the acid and the organic polymers

together with proteins and calcium from the dentinal liquor. These plugs are stable for 6 to 15 months.

The desensitizers of the present invention are not comparable with a dentifrice. Typically, a desensitization achieved by the use of a dentifrice only lasts for one day, i.e. a dentifrice has to be used daily. Patell pertains to stabilized pharmaceutical compositions comprising gelatin coated pharmaceutically active dosage units and is thus concerned with a different technical field. A skilled person interested in providing improved compositions for desensitizing teeth would not have considered the teachings of Patell.

For at least these reasons, Applicants submit that the proposed combination of Norfleet, Asano, and Patell does not render obvious the present invention. Withdrawal of the record rejection and allowance of all claims is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

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